

MISSOURI BOARD OF PHARMACY

ANNUAL REPORT



FY 2021

Michael L. Parson, Governor
State of Missouri

Chlora Lindley-Myers, Director
Department of Commerce and Insurance

Sheila Solon, Acting Division Director
Division of Professional Registration



Michael L. Parson
Governor
State of Missouri

Sheila Solon, Acting Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of
Commerce and Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091 PHONE
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
www.pr.mo.gov/pharmacists
email: MissouriBOP@pr.mo.gov

To The Honorable Governor Michael L. Parson:

In compliance with § 338.140.3, RSMO, the Missouri Board of Pharmacy is pleased to submit its Annual Report which contains the proceedings of the Board for the fiscal year ending June 30, 2021 ("FY 21"). The Board's mission is to protect the public in the regulation of pharmacy practice. The Board of Pharmacy is pleased to report another successful year.

Respectfully yours,
MISSOURI BOARD OF PHARMACY
By:

A handwritten signature in black ink, appearing to read "K A Grinston", written over a horizontal line.

Kimberly Grinston
Executive Director



Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

FY 2021

Board Members

James Gray, PharmD., President
Christian Tadrus, PharmD., Vice-President
Colby Grove, PharmD., Member
Douglas Lang, R.Ph., Member
Christina Lindsay, PharmD., Member
Pamela Marshall, R.Ph., Member
Anita K. Parran, Public Member

Missouri Board of Pharmacy

P.O. Box 625
3605 Missouri Boulevard
Jefferson City, Missouri 65102
Phone (573) 751-0091
Fax (573) 526-3464
Web Site <http://www.pr.mo.gov/pharmacists>
Email: MissouriBOP@pr.mo.gov

Kimberly A. Grinston, J.D., Executive Director

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Executive Summary



This Annual Report covers the activities of the Missouri Board of Pharmacy from July 1, 2020 to June 30, 2021 (FY21). The Board is pleased to announce another successful regulatory year as reflected below:

Board Operations

- The Board held thirty (30) meetings during FY 21, including, twenty-two (22) virtual meetings, seven (7) email ballot meetings and one (1) Board sub-committee meeting [Rules Sub-Committee]. In addition to Board meetings, the Missouri Hospital Advisory Committee established by § 338.165, RSMo, held six (6) virtual meetings facilitated by the Board.
- Meeting totals declined from the unprecedented number of meetings held during FY 20 to address the initial stages of the COVID-19 pandemic. Despite the decline, FY 20 Board meeting totals constitute a 30% increase from FY 19 and a 42% increase from FY 18.
- The Board continued its efforts to address the COVID-19 pandemic in collaboration with state and federal partners. Board activities included promulgating two (2) emergency COVID-19 related amended rules, authorizing expedited application procedures for new applicants to ensure prompt authorization to practice, and implementing modified inspection/investigation procedures.
- As part of its ongoing efforts to protect patients through voluntary compliance, the Board hosted six (6) educational webinars. Educational programs were free and Board approved for pharmacist continuing education.

Financial Overview

- The Board's total appropriation and authorized transfers for FY 21 were \$3,737,573. Board expenditures totaled \$2,530,897.22, representing a 5.5% decrease from FY 20.
- Board revenue remained consistent with a minor 1.7% increase.

Licensing Summary

- Total Board licensees/registrants decreased by 11% to 37,439 total licensees/registrants, with intern pharmacists (-14%) and pharmacy technicians (-18%) experiencing the largest decrease. The decrease may be partially attributable to fewer intern pharmacists and pharmacy technicians renewing their licenses during the COVID-19 pandemic.
- 37,439 licensees/registrants were licensed/registered by the Board at the close of FY21, as reflected below:
 - o Drug Distributors (1,336)
 - o Drug Distributor Manufacturer Registrants (101)
 - o Drug Outsourcers (45)
 - o Intern Pharmacists (1,699)
 - o Pharmacists- Active & Inactive (11,684)
 - o Pharmacists- Temporary (14)
 - o Pharmacies (2,663)
 - o Pharmacy Technicians (19,706)
 - o Third-party Logistics Providers (191)
- While total license counts decreased, new licensees/registrants increased by 10.55% to 6,650 new licenses/registrations issued during the fiscal year. FY 21 totals represent the first increase in new licensees/registrations since FY 18.
- Although new licensees/registrants increased, newly licensed pharmacists decreased by 25.4% representing the largest decrease in recent Board history. This decrease is likely attributable to fewer pharmacists applying for Missouri licensure due to COVID-19. Additionally, state and federal COVID-19 related emergency orders/declarations were issued during FY 21 that authorized non-resident pharmacists and pharmacy technicians to

Executive Summary



temporarily provide pharmacy services in Missouri without a Missouri pharmacist license to assist with emergency care/immunizations.

- All Missouri counties now have a Missouri-licensed pharmacy for the first time since FY 13. The total number of licensed pharmacies increased in twenty (20) counties/areas, compared to one (1) county in FY 20. Eighteen (18) counties/areas experienced a decrease in pharmacies, compared to 37 counties in FY 20.

Complaint Handling

- The Board received/opened 468 new complaints in FY 21, representing a 22% decrease from FY 20. The decrease is likely attributable to fewer patients physically visiting pharmacies in FY 21 due to COVID-19 and fewer tax compliance cases referred to the Board by the Missouri Department of Revenue.
- The Board issued final dispositions on approximately 574 complaints/cases, representing a 7% decrease from FY 20. *Includes dispositions on complaints received in prior fiscal years.
- Five-hundred and fifty-eight (558) of the 574 complaint/case dispositions were non-tax related, while sixteen (16) cases were tax referrals. Of the 558 non-tax related complaint dispositions, 88.5% resulted in no disciplinary action (494 cases), while disciplinary action was taken in the remaining 11.4% of cases (64 cases).

Disciplinary Actions

- The Board issued disciplinary action in eighty-one (81) cases in FY 21, with 16 tax-related suspensions and 65 practice-related disciplinary actions.
- Practice related discipline remained stable with a slight 1.5% increase. Tax-related disciplinary cases increased from zero (0) cases in FY 20 to sixteen (16) tax-related suspensions/actions in FY 21, as the Dept. of Revenue resumed referrals of tax-related cases. Despite the increase, total tax-related disciplinary cases were 60% lower than FY19 and 94.6% lower than FY18.

Inspections/Investigations

- The Board resumed a modified inspection schedule in FY 21 as part of its continued COVID-19 precautions, with limited inspections of COVID-19 high risk facilities (e.g., long-term care, infusion/chemotherapy facilities)
- Under the modified inspection schedule, 1,073 regulatory inspections were conducted, representing a 10% increase from FY 20. The Board anticipates returning to a full inspection schedule in 2022.
- Despite COVID-19 restrictions, total investigations remained consistent with a minor 2.3% decrease (206 investigations)

Compounded Drug Testing

- Pursuant to § 338.150, RSMo, the Board conducts a testing program for drug preparations compounded by licensed pharmacies. 73.8% of products tested in FY21 were satisfactory while 26.2% were unsatisfactory. Failing potency results ranged from zero to 124.8%.

Executive Summary



Rulemaking

- The Board continued its review of Missouri's pharmacy rules to ensure appropriate and consistent regulation and prompt access to care during COVID-19.
- Twelve (12) administrative rules were adopted or amended in FY 21, including two (2) COVID-19 related emergency rule amendments. The Board also submitted five (5) legislative proposals for approval by the Governor.

Rx Cares for Missouri

- The Board continues its operation of the Rx Cares for Missouri Program established by § 338.142 to promote medication safety and to prevent prescription drug abuse, misuse and diversion in Missouri. As part of Rx Cares for Missouri, the Board established the Rx Cares Medication Destruction and Disposal Program (the Program) which provides a statewide drug take-back program for collecting/disposing of unused controlled substances, as authorized by § 338.142, RSMo.
- Participants in the statewide medication destruction Program increased by 53% from sixty-two (62) participants in FY20 to Ninety-Five (95) participants in FY 21. Program expenditures totaled \$ 126,900.
- Approximately 5,443 pounds of medication were destroyed during the fiscal year as part of the Program, representing a 550% increase from the Program's first full implementation year in FY 20.

About the Board



Mission Statement

The Board's mission is to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:

- Protects the public from incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty;
- Licenses only qualified and competent professionals, and;
- Ensures compliance with professional standards and federal and state pharmacy law.

ABOUT THE MISSOURI BOARD OF PHARMACY

The Missouri Board of Pharmacy was statutorily created in 1909 and has served the citizens of Missouri through the regulation of pharmacy practice for over 100 years. The Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Department of Commerce and Insurance.

MEMBERSHIP

The Board consists of seven (7) members, including, six (6) licensed pharmacists actively engaged in the practice of pharmacy and one (1) public member. By statute, at least one member must provide pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis. Board members are appointed by the Governor and confirmed by the Missouri Senate. All members hold office for five (5) years from the date of their appointment or until their successors have been appointed and qualified. The Board annually elects a president and vice-president, each of whom serve one (1) year terms.

FUNCTIONS

Pursuant to Chapter 338, RSMo, the Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- Ensuring compliance with Chapter 338, RSMo, and the rules of the Board;
- Licensing/registering pharmacists, pharmacy technicians, intern pharmacists, pharmacies, drug distributors, drug outsourcers and third-party logistics providers;
- Investigating complaints within the Board's statutory jurisdiction;
- Disciplining licensees which may include, public censure, probation, suspension or revocation of a licensee/registrant;
- Inspection of pharmacies, drug distributors, drug outsourcers and third-party logistics providers; and
- Approval of preceptors and intern training facilities.

Board Operations



General Board Operations

The Board held thirty (30) meetings during FY 21, including, twenty-two (22) virtual meetings, seven (7) email ballot meetings and one (1) Board sub-committee meeting [Rules Sub-Committee].* In addition to Board meetings, the Missouri Hospital Advisory Committee established by § 338.165, RSMo, held six (6) virtual meetings facilitated by the Board.*

Meeting totals declined from the unprecedented number of meetings held by the Board during FY 20 to address the initial stages of the COVID-19 pandemic. Despite the decline, FY 20 Board meeting totals constitute a 30% increase from FY 19 and a 42% increase from FY 18.

*All meetings were held virtually due to COVID-19 precautions; Public members were able to access and virtually attend open session meetings.

Staff

The following staff were employed by the Board at the close of FY21:

Staff

- **Kimberly Grinston, J.D., Executive Director**
- Jennifer Boehm, Administrative Coordinator
- Angela Fulton, Pharmacy Technician Coordinator
- Kimberly Hatfield, Compliance Coordinator
- Laura Henke, Pharmacy/Drug Distributor Coordinator
- Laura Warden, Pharmacist Coordinator
- Jasmine Whittier, Pharmacist Coordinator

Inspectors

- **Tom Glenski, R.Ph., Chief Inspector**
- Bennie Dean, R.Ph.
- Katie DeBold, PharmD.
- Andrea “Andi” Miller, PharmD.
- Scott Spencer, R.Ph.
- Lisa Everett, R.Ph.
- Daniel Vandersand, R.Ph.
- Elaina Wolzak, R.Ph.
- Barbara Wood, R.Ph.

COVID-19 Pandemic:

The Board continued its efforts to address the COVID-19 pandemic in collaboration with state and federal partners.

A series of safety measures were implemented to maintain core Board functions during the COVID-19 pandemic while reducing the risk of COVID-19 exposure for staff and the public.

- All Board meetings were conducted virtually during the FY 21 with virtual access for public attendees. The Board also hosted four (4) licensee webinars that included updates on COVID-19 regulatory changes/COVID-19 vaccine deployment.
- The Board continued its modified risk-based inspection schedule, with limited non-emergency inspections of locations servicing vulnerable patient populations (e.g., long-term care facilities, infusion/chemotherapy clinics). A COVID-19 inspection screening survey was implemented, along with mandatory staff safety precautions (e.g., face masks, daily temperature check, equipment disinfection/sanitation).
- Expedited application procedures were implemented for drug distributors and federal partners dispensing/distributing COVID-19 vaccines, and non-resident pharmacists/licensees assisting with COVID-19 response efforts. Expedited application procedures were also initiated for 2021 pharmacy school graduates from Missouri schools and bordering states, to ensure prompt licensure/authorization to work.
- The Board promulgated two (2) emergency rule amendments to ensure prompt access to patient care/medication during the pandemic, including:
 - a. 20 CSR 2220-5.020 (Drug Distributor Licensing Requirements): Provides a Missouri drug distributor



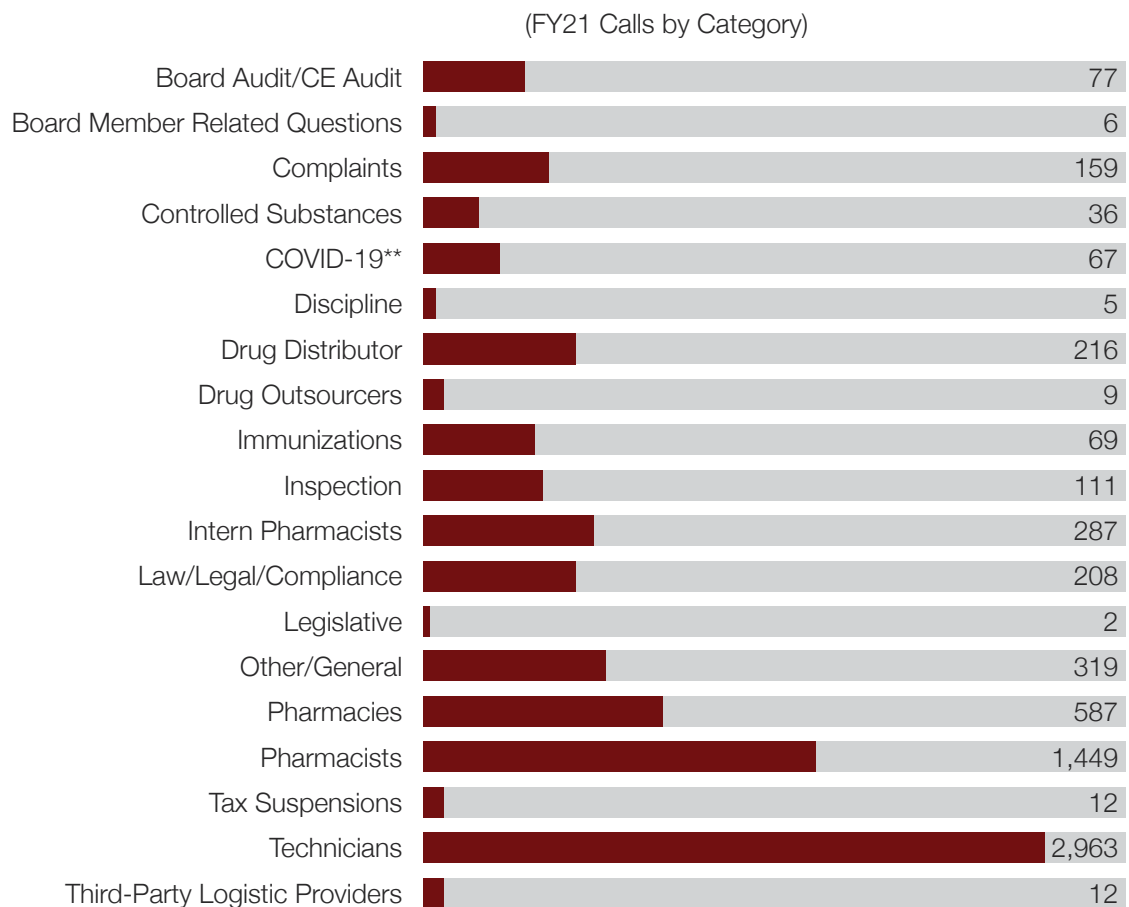
license is not required for facilities distributing medication to treat/immunize patients during a state or federally declared emergency/disaster, or distributing medication/vaccines subject to the U.S. Food and Drug Administration's emergency use authorization for a public health emergency.

- b. 20 CSR 2220-6.040 (Administration of Vaccines Per Protocol): Allows pharmacy technicians to administer vaccines by protocol under the direct supervision of a Missouri-licensed pharmacist.

Office Activities

The Board received/responded to 6,594 telephone calls during FY 21, representing a 16.6% increase from FY 20. This increase is partially attributable to increased calls related to COVID-19.

Major call topic areas are identified below:



* Pharmacist category includes licensing, continuing education and audit related questions.

**COVID-19 related calls may have also been recorded in other categories (e.g. Law/Legal/Compliance/Immunizations/Pharmacy/etc).



Education/Training

As part of its ongoing efforts to promote voluntary compliance, the Board hosted the following compliance webinars in FY 21 (participants were awarded free continuing education credit):

- MO HealthNet Pharmacy Update
- 2020 Legislative Update
- 2020 Chief Inspector Compliance Update (Q&A Session)
- COVID-19 & Regulation Update
- 2021 Regulation Update
- 2021 New Graduate/MPJE Updates

** Section 324.035 was enacted in FY 20 which prohibits professional/occupational boards within the Division of Professional Registration from using Board funds to provide designated continuing education classes.

Gold Certificates

The following individuals received Gold Certificates during FY 21 representing fifty (50) years of licensure as a Missouri pharmacist:

- Robert L Alexander
- Joseph F Bridges
- Carolyn L Bussen
- William E Clasen
- Jimmie L Crain
- Ronald Daniel
- Lamoyne Dungan
- Daniel J Feuer
- Gary D Fox
- David F Hagedorn
- Jimmy L Hart
- George I Juenger
- Larry L King
- Robert F Manchester
- John C Martin
- James J Naber
- Frank J Nuber
- Margaret A Roberts
- Mary A Robinson
- Richard C Sachan
- Richard W Tiburzi
- Mary Anne S Toll
- William Z Way
- David T Willard
- Neil A Yant

Financial Summary



Financial Overview:

The Missouri Board of Pharmacy's appropriation for the fiscal year ending June 30, 2020, was as follows:

Personal Service	\$ 1,239,241.00
Expense and Equipment	\$ 1,418,974.00
Criminal History Fund	\$ 5,000.00
Transfers*	\$ 1,074,358.00
	<hr/>
	\$ 3,737,573.00

Of the amount appropriated, the Board expended \$ 2,530,897.22 in FY 21 as follows:

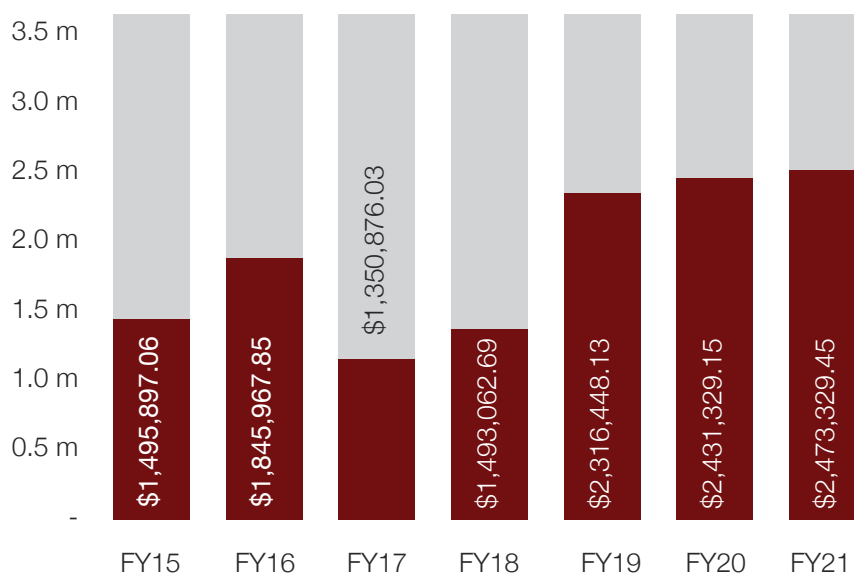
Personal Service	\$ 1,209,281.96 (48%)
Expense and Equipment	\$ 398,526.62 (16%)
Transfers*	\$ 923,088.64 (36%)

*Transfers include costs/transfers for rent, the Division of Professional Registration, IT transfers, licensee refunds, attorney general services, Administrative Hearing Commission, DIFP Allocated Expenses and OA Allocated Expenses.

Revenue Received:

The Board of Pharmacy is statutorily obligated to establish fees as necessary to administer the provisions of Chapter 338, RSMo. Section 338.070, RSMo, provides fees must be appropriate so that revenue produced does not substantially exceed the cost and expense of administering Chapter 338.

To ensure compliance with § 338.070 and to address an unanticipated 55% increase in revenue in FY 19, the Board lowered renewal fees for pharmacies, drug distributors, drug outsourcers and third-party logistics providers in FY 20. As a result, Board revenues in FY 21 remained consistent with a minor 1.7% increase.

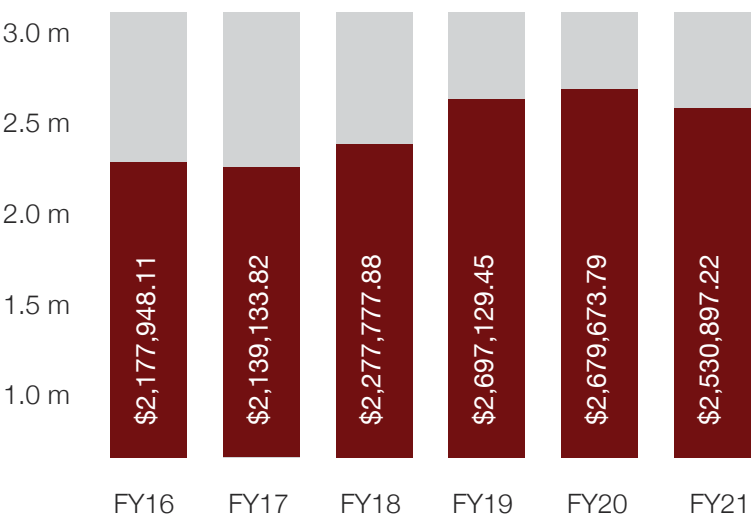


The Board will continue to monitor revenue trends to ensure compliance with § 338.070, RSMo.



Board Expenditures:

Board expenditures decreased by 5.5% as reflected below:





Licensing Summary

Pursuant to Chapter 338, RSMo, the Board licenses and regulates pharmacists, intern pharmacists, pharmacy technicians, pharmacies, drug distributors, drug outsourcers and third-party logistics providers.

The Board's total licensee/registrant count decreased by 11% to 37,439 total licensees/registrants. The largest decreases occurred in intern pharmacists and pharmacy technicians, as reflected below:

- Drug Distributors (+2.8%)
- Drug Distributor Registrants (-.9%)
- Drug Outsourcers (+15.38%)
- Intern Pharmacists (-14%)
- Pharmacies (+1.7%)
- Pharmacists (Active and Inactive) (-1.16%)
- Pharmacy Technicians (-18%)
- Temporary Pharmacists (-6%)
- Third-Party Logistics Providers (+14.4%)

The FY 21 decrease reverses the uncharacteristic 11% increase in licensing totals experienced in FY 20 and brings licensing totals into alignment with pre-FY 20 licensing data.

While total license counts decreased, new licensees/registrations increased by 10.5% with 6,650 new licenses/registrations issued in FY 21. FY 21 totals represent the first increase in new licensees/registrations since FY 18. FY 21 new license/registration totals are reflected below:

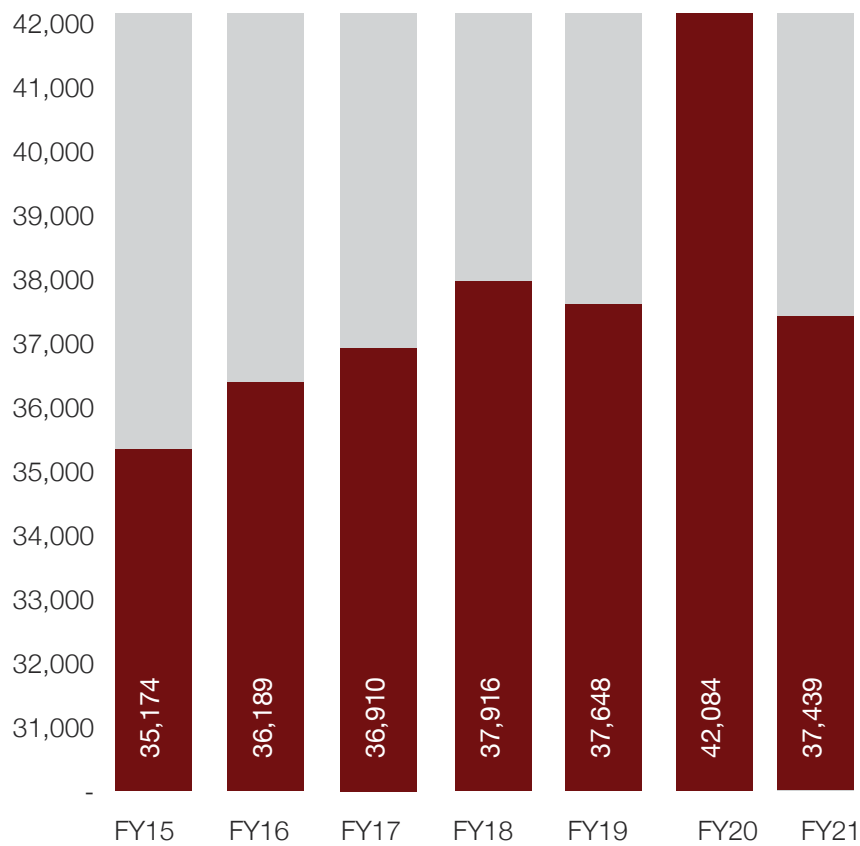
- Drug Distributors (-17.5%)
- Drug Distributor Registrants (-69.4%)
- Drug Outsourcers (+40%)
- Intern Pharmacists (-2.5%)
- Pharmacies (-3.7%)
- Pharmacists (Active and Inactive) (-25.4%)
- Pharmacy Technicians (+18.2%)
- Third-Party Logistics Providers (-29.7%)

Licensing totals at the close of FY 21 are provided by classification below:

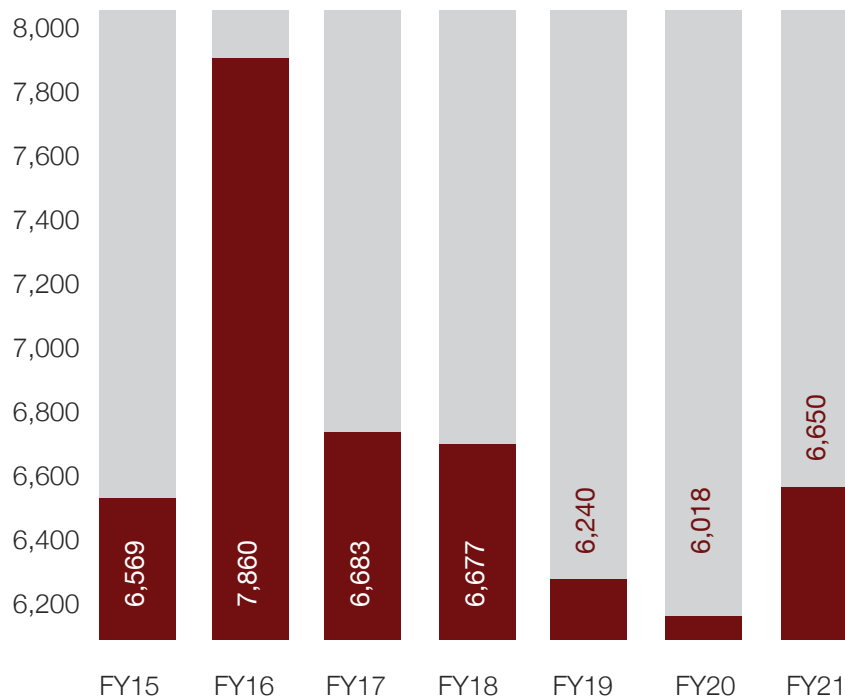
LICENSING TOTALS	
Drug Distributors (licensed & temporary)	1,336
Drug Distributor Manufacturer Registrants	101
Intern Pharmacists	1,699
Pharmacists (active and inactive)	11,684
Pharmacists (temporary)	14
Pharmacies (instate, non-resident and temporary)	2,663
Pharmacy Technicians	19,706
Drug Outsourcers	45
Third-Party Logistics Provider (licensed & temporary)	191
TOTAL	37,439



Total Licensees/Registrants by Fiscal Year



New Licensees/Registrants by FY

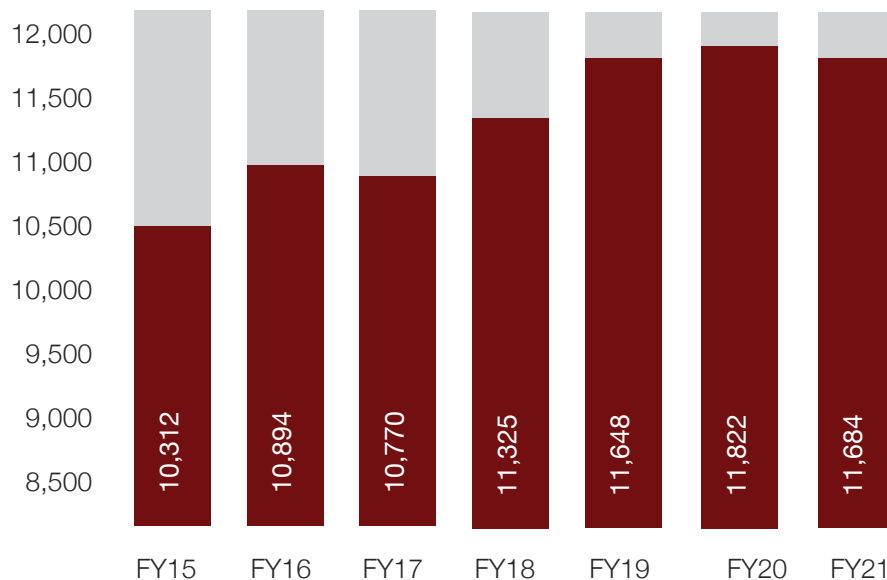


Licensing



Pharmacists:

Total licensed pharmacists remained consistent with a minor 1% decrease:



The number of active vs. inactive Missouri pharmacists both resident and non-resident are reflected below. The Board experienced a historic 58% increase in inactive licensees in FY 19 that was followed by a 51% decrease in FY 20. Total inactive pharmacists decreased once again in FY 21 by 14%, however, FY 21 numbers are consistent with inactive licensee data prior to the FY 19 increase.

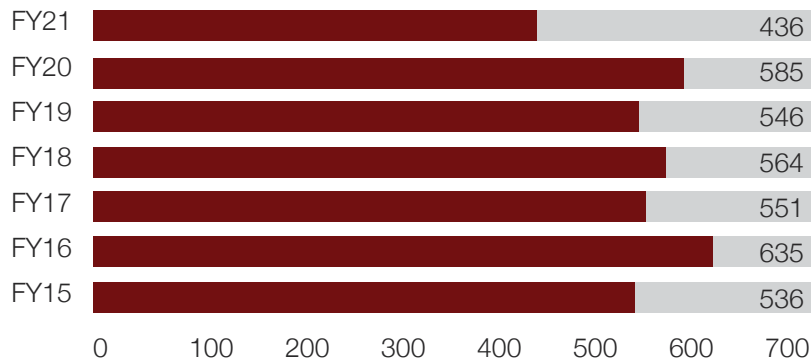
Active Licensees	11,375
Male	4,934
Female	6,528
Inactive Licensees	309
TOTAL LICENSED PHARMACISTS	11,684

**Inactive pharmacists are not authorized to practice in Missouri but remain licensed. Pharmacists are only allowed to go inactive during the renewal period.



Number of New Pharmacist Licenses Issued

Newly licensed pharmacists decreased by 25.4%, as reflected below:



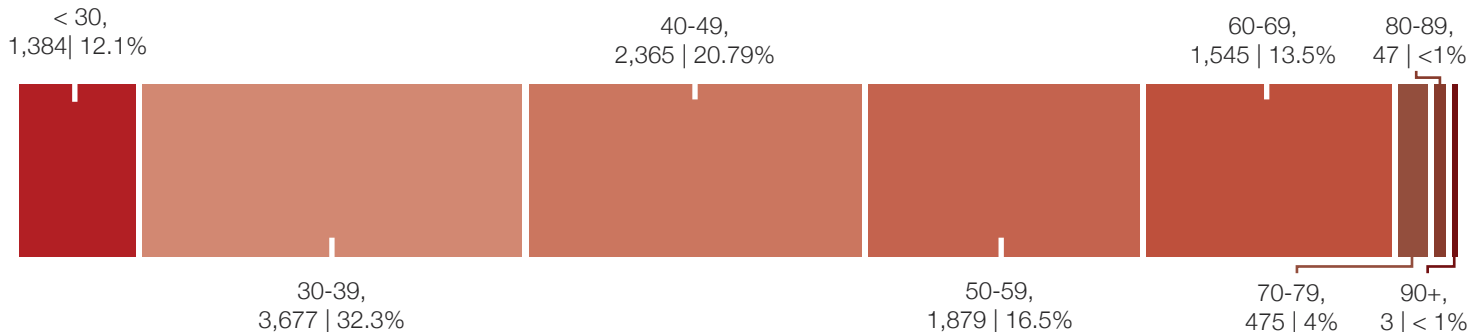
Although the Board historically experiences a decrease in new pharmacists in renewal fiscal years as with FY 21, the FY 21 new pharmacist decrease is the largest in recent Board history. The identified decrease is likely attributable to the COVID-19 pandemic. Additionally, state and federal COVID-19 related emergency orders/declarations were issued during FY 21 that authorized non-resident pharmacists and pharmacy technicians to temporarily provide pharmacy services in Missouri without a Missouri pharmacist license to assist with emergency care/immunizations.



Active Pharmacists By Age Group (Resident and Non-Resident) [#,%]

No significant changes occurred in the number of active pharmacists categorized by age. . Approximately 43% of active Missouri pharmacists are age 39 and under with the remaining 57% at age 40 or above.

(Pharmacist Distribution by Age)



Pharmacists Residing in Missouri

No significant changes occurred in actively licensed resident vs. non-resident pharmacists. Approximately 60.7% of pharmacists reported a Missouri address as reflected below:

Resident Pharmacists	6,904
Non-Resident Pharmacists	4,471
Total Missouri Resident Pharmacists	11,375

Administration & Immunizations:

Pursuant to § 338.010, RSMo, pharmacists are authorized to administer medication by prescription order and to administer vaccines pursuant to a protocol with a Missouri-licensed physician, upon filing a Notification of Intent with the Board. At the end of FY 21:

- 3,258 pharmacists were authorized to administer medication by prescription, representing a 4% decrease from FY 21.
- 3,633 pharmacists were authorized to administer immunizations by protocol, representing a 1.3% decrease.

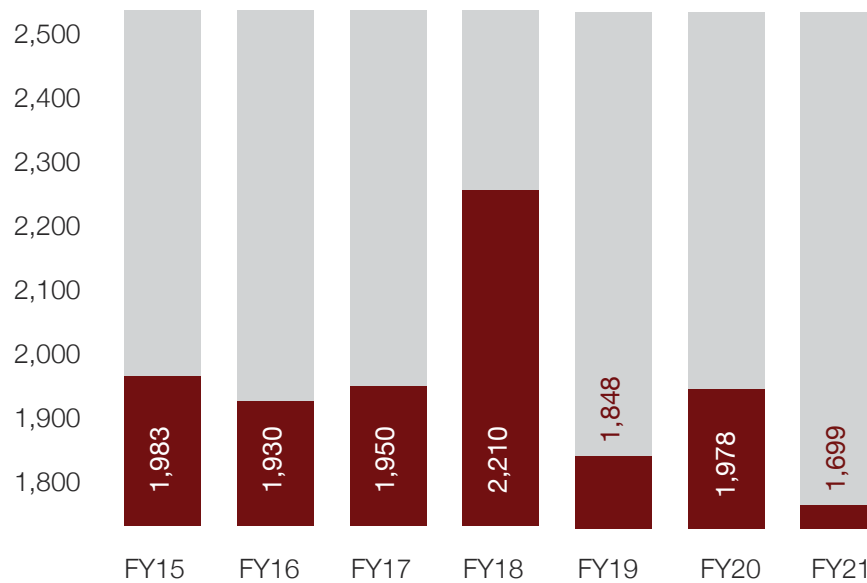
Medication Therapy Services:

Section 338.010, RSMo, authorizes the Board to issue a Certificate of Medication Therapeutic Plan Authority (MTS certificate) which allows pharmacists to provide medication therapy services. A total of 2,548 pharmacists held a MTS certificate at the end of FY 21, representing a 27% decrease from FY20. This decrease is consistent with the overall 25.4% decrease in new pharmacist applicants during FY 21.



Intern Pharmacists

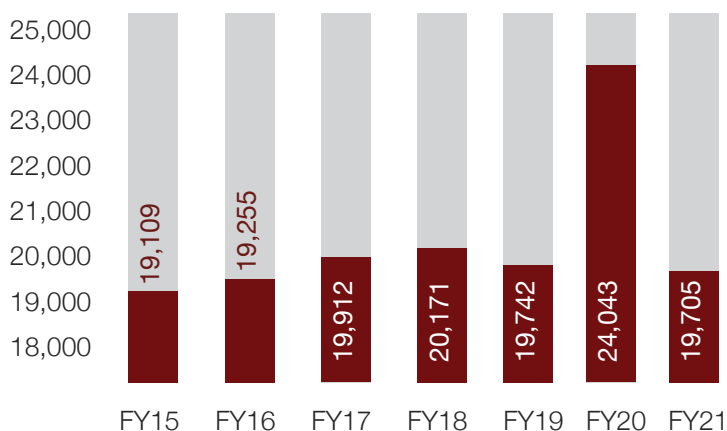
Licensed intern pharmacists decreased by 14% as reflected in the chart below. Four-hundred and eighty-three (483) new intern pharmacist licenses were issued, representing a slight 2.5% decrease in new intern pharmacist licensees from FY 20.





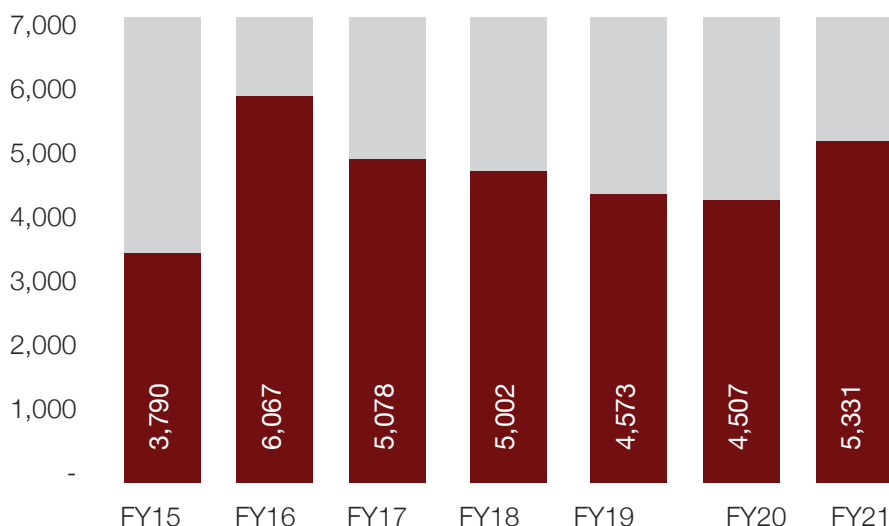
Pharmacy Technicians:

Registered pharmacy technicians decreased by 18%. This decrease may be partially attributable to fewer pharmacy technicians choosing to renew their registrations during the COVID-19 pandemic. Notably, the decrease follows an uncharacteristic 21.8% increase in total pharmacy technicians during FY 20 and more closely aligns pharmacy technician totals with pre-FY 20 licensing data.



New Pharmacy Technician Registrations Issued

While total pharmacy technician registrants decreased significantly in FY 21, new pharmacy technician registrants increased by 18%. Notably, the FY 21 increase reverses a decline in new applicants experienced in FY 17 – FY 20.



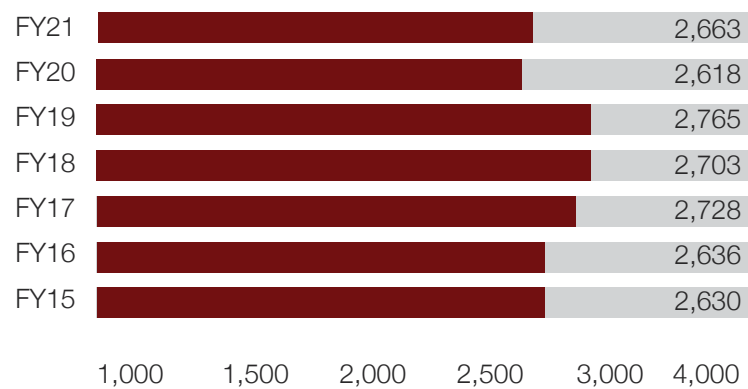


Pharmacy Summary:

PHARMACY PERMIT TOTALS	
Instate Pharmacies	1,459
Non-Resident Pharmacies	1,199
Temporary Pharmacies	5
TOTAL	2,663

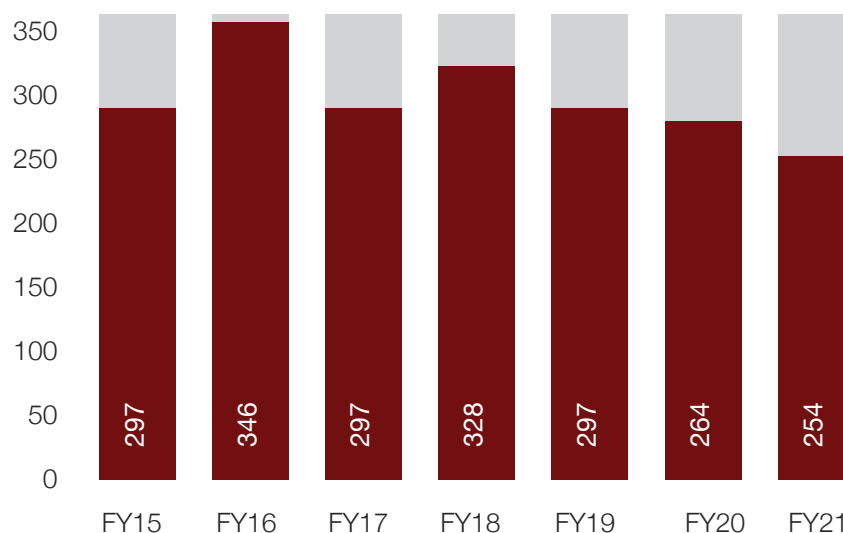
Total pharmacies remained consistent (both in-state and non-resident) with a minor 1.7% increase

Pharmacy Permitholders By Fiscal Year



New Pharmacy Permits Issued

New pharmacy permits decreased by 3.7% , representing the 3rd consecutive fiscal year with a decline.





Pharmacy Permits by Classification*

(The totals below will not equal the total # of licensed pharmacies. Pharmacies may hold multiple classifications and could be reflected in more than one category).

(Class, Total # in Class/ Missouri Located Pharmacies in Class)	
Class A: Community/Ambulatory	2,123 (1,238 Missouri)
Class B: Hospital Pharmacy	159 (148 Missouri)
Class C: Long-Term Care	915 (818 Missouri)
Class D: Nonsterile Compounding	752 (309 Missouri)
Class E: Radiopharmaceutical	31 (10 Missouri)
Class F: Renal Dialysis	12 (1 Missouri)
Class G: Medical Gas	11 (9 Missouri)
Class H: Sterile Compounding	356 (107 Missouri)
Class I: Consultant Services	24 (3 Missouri)
Class J: Shared Services	1,253 (987 Missouri)
Class K: Internet	45 (1 Missouri)
Class L: Veterinary	59 (5 Missouri)
Class M: Specialty (Bleeding Disorder)	130 (16 Missouri)
Class N: Automated Dispensing System (Health Care Facility)	30 (30 Missouri)
Class O: Automated Dispensing System (Ambulatory Care)	0
Class P: Practitioner Office/Clinic	0
Class Q: Charitable Pharmacy*	---
Class R: Remote Dispensing Site Pharmacy*	4 (4 Missouri)

*Final rules pending at the end of FY20

Notably:

- 70% of Class H (Sterile Compounding) licensees are non-resident pharmacies,
- 67.% of Class E (Radiopharmaceutical) licensees are non-resident pharmacies
- 87.6% of Class M (Bleeding Disorder) licensees are non-resident pharmacies.
- 89% of Class C (Long-Term Care) pharmacies are located in Missouri.

[illegible]

- All Missouri counties currently have a Board licensed pharmacy (Ralls County did not have a licensed pharmacy from FY14 – FY 20).
- Number of counties with < 10 pharmacies: 91
- Number of counties with 100+ pharmacies: 2 (St. Louis & Jackson County)
- Pharmacy totals increased in twenty (20) counties/areas: Atchison, Boone, Clay, Franklin, Henry, Howell, Jackson, Jasper, Jefferson, Marion, Moniteau, Ralls, Scott, St. Charles, St. Francois, St. Genevieve, St. Louis City [+10], St. Louis County [+21], Warren, Wayne. This data is in marked contrast to FY 20 when only one (1) Missouri county increased in pharmacy totals.



- Eighteen (18) counties/areas experienced a decrease in pharmacies in FY 21, compared to 37 counties in FY 20, as reflected below:
 - Adair (-2)
 - Audrain (-1)*
 - Buchanan (-1)
 - Chariton (-1)*
 - Christian (-4)
 - Crawford (-2)*
 - Douglas (-1)
 - Greene (-9)*
 - Henry (-1)
 - Lewis (-1)
 - Lincoln (-2)
 - Phelps (-1)
 - Platte (-2)
 - Polk (-1)*
 - Randolph (-1)
 - Stoddard (-1)*
 - Taney (-2)*
 - Webster (-1)*
- *Counties also declined in FY 20.

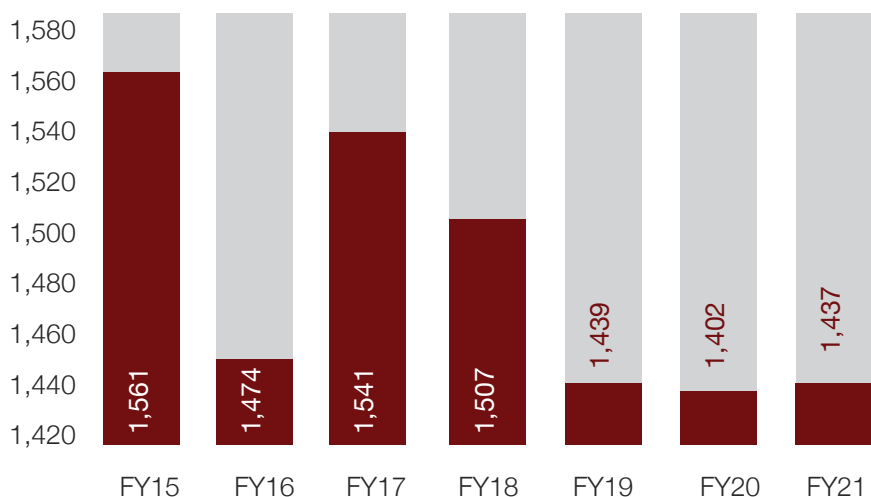


Drug Distributor Summary:

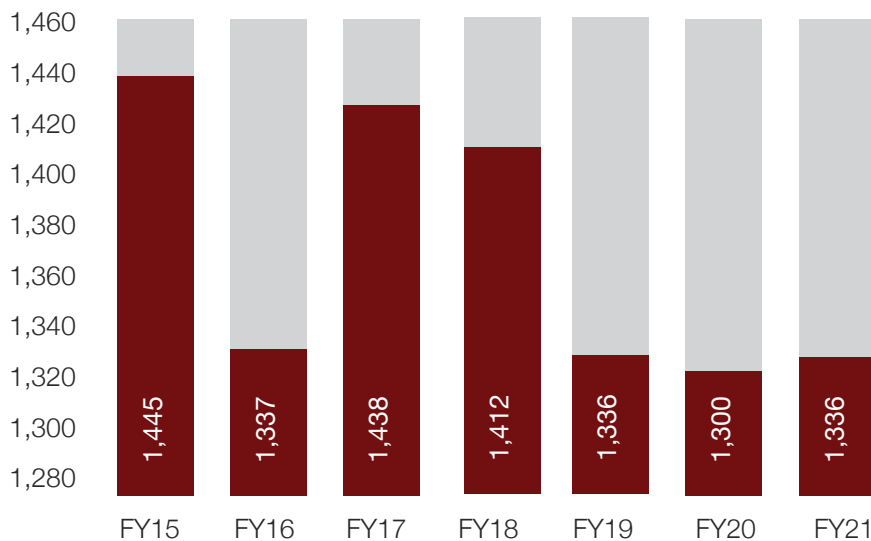
All in-state drug companies that ship/transfer legend pharmaceuticals or drug-related devices are required to be licensed as a Missouri drug distributor. Additionally, out-of-state drug companies or manufacturers that ship/transfer legend drugs or drug related devices into Missouri must hold a Missouri drug distributor license.

TOTAL DRUG DISTRIBUTORS & DRUG DISTRIBUTOR REGISTRANTS BY FISCAL YEAR

Total licensed drug distributors and drug distributor registrants remained consistent with a 2.4% increase (1,336 drug distributors and 101 drug distributor registrants).



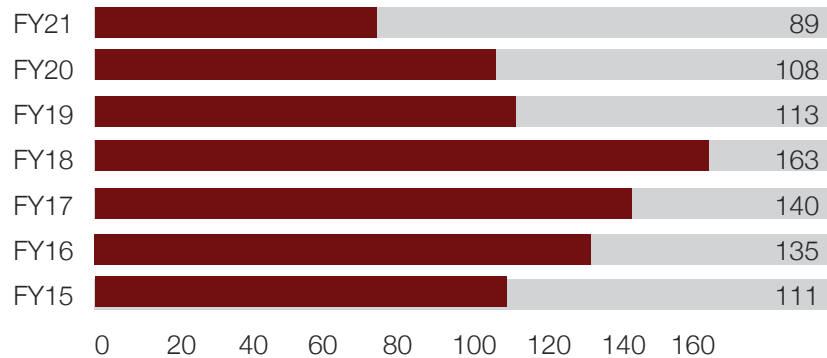
TOTAL DRUG DISTRIBUTORS BY FY





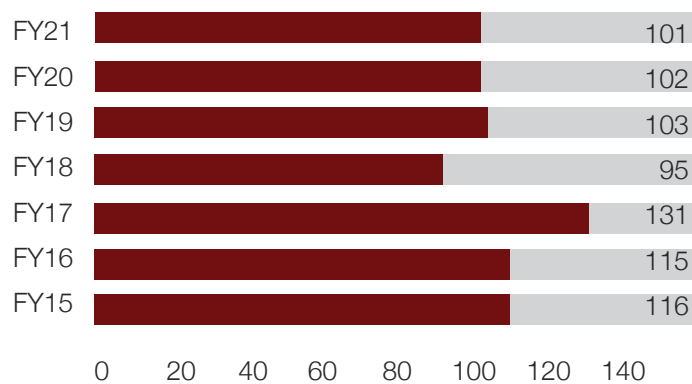
NEW DRUG DISTRIBUTORS LICENSED

Newly licensed drug distributors decreased by 17.5%, representing the third consecutive fiscal year decline:



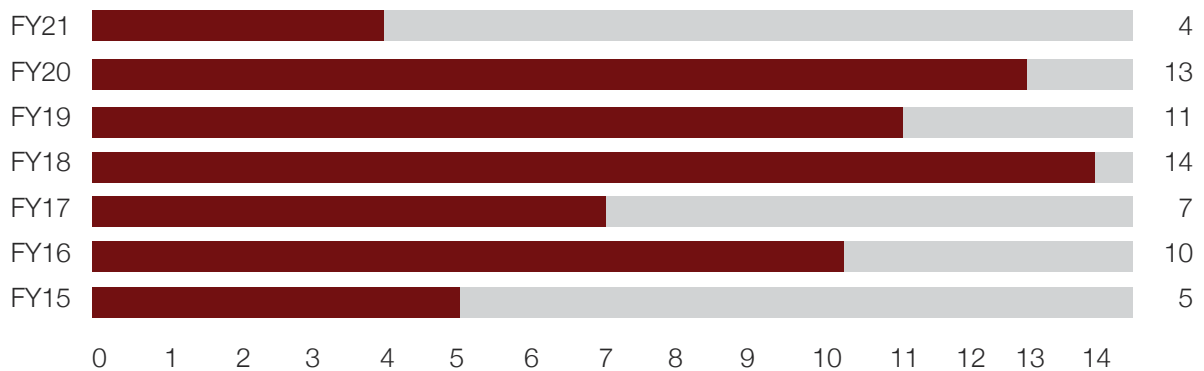
TOTAL DRUG DISTRIBUTOR REGISTRANTS BY FY

Total drug distributor registrants remained consistent:



NEW DRUG DISTRIBUTOR REGISTRANTS

The number of new drug distributor registrants remained historically low:





DRUG OUTSOURCERS/THIRD -PARTY LOGISTICS PROVIDERS

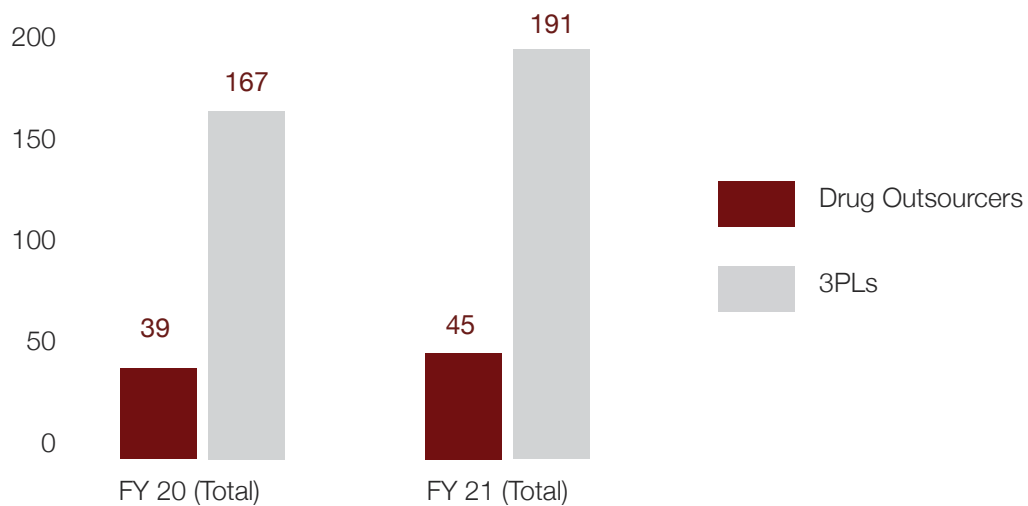
The Board began issuing drug outsourcer and third-party logistics provider (3PL) licenses in the fall of 2018

- Total 3PL licensees increased by 14.4% [FY 20 (167); FY 21 (191)]
- Total drug outsourcer licensees increased by 15% [FY 20 (39); FY 21 (45)]

New applicants for both license classes remained historically low:

- New 3PL licensees [FY 20 (47); FY 21 (33)]
- New drug outsourcer licensees [FY 20 (5); FY 21 (7)]

DRUG OUTSOURCERS/THIRD -PARTY TOTALS



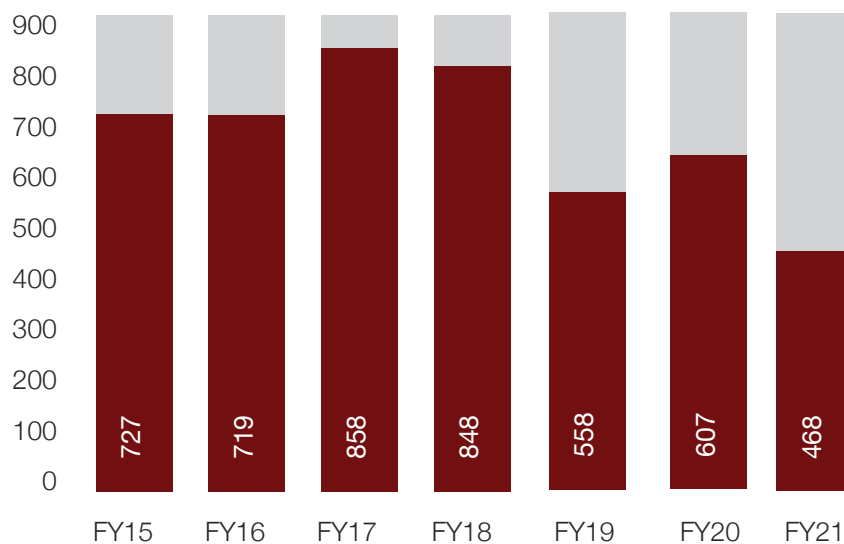
Complaint Summary



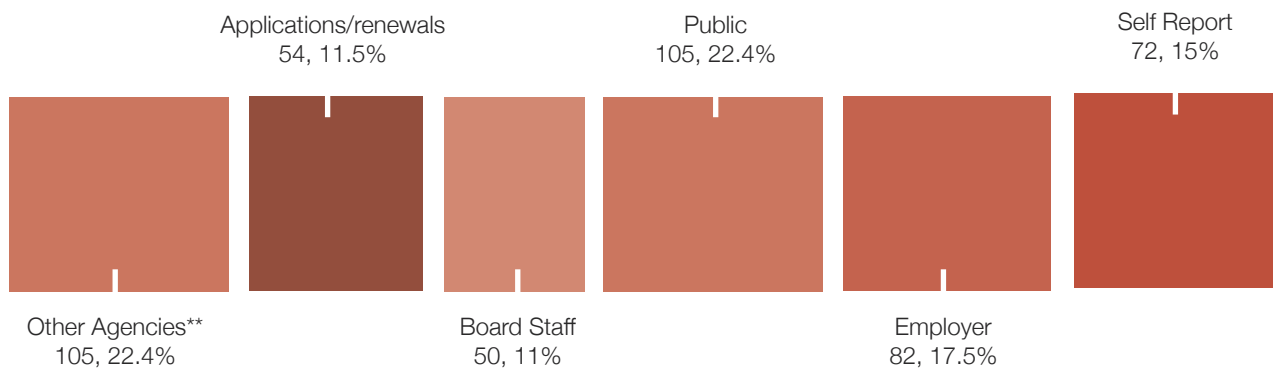
Complaint Summary

All matters investigated or officially reviewed by the Board are recorded as complaints and processed according to Board procedures. The Board received/opened 468 new complaints in FY 21, representing a 22% decrease from FY 20. The decrease is likely attributable to fewer patients physically visiting pharmacies in FY 21 due to COVID-19 related closures/quarantines. Additionally, the Missouri Department of Revenue referred a significantly lower number of tax compliance cases/complaints to the Board for the third consecutive fiscal year (FY 21= 16 complaints). The Board has been advised the Dept. of Revenue intends on fully resuming tax compliance referrals in FY 22, after implementation of new Department of Revenue reporting software.

Complaints Handled by FY



Complaints by Source



*Complaints received from other agencies increased by 59% attributable to a marked increase in non-resident disciplinary actions reported to the Board by the National Association of State Boards of Pharmacy (NABP) Clearinghouse***

Complaint Summary



FY21 COMPLAINTS BY CATEGORY

Adulterated Drugs	5
Advertising or Marketing	1
Compounding	11
Confidentiality	5
Counseling	1
Criminal History	12
Disciplinary Action in Another State	129
Dispensing Error	18
Drug Diversion	17
Drug Losses	6
Expired Drugs in Active Inventory	1
Fraudulent Prescription	7
Fraud - Unspecified	3
Immunization/Administration	3
Impairment/Addiction	8
Improper Controls	68
Improper/Unauthorized Dispensing	36
Incompetence	4
Inspection Violations	1
Insurance Fraud	4
Licensure Applicant	32
Misbranding	1
Other	4
Recordkeeping	4
Repackaging/Packaging	2
Tax Suspensions (Dept. of Revenue/Missouri Courts)	16
Theft (Non-drug)	13
Unlicensed Activity	22
Unprofessional Conduct	23
Unsanitary Pharmacy	1
Unsupervised Activity	3
Violation of Discipline	7
TOTAL	468

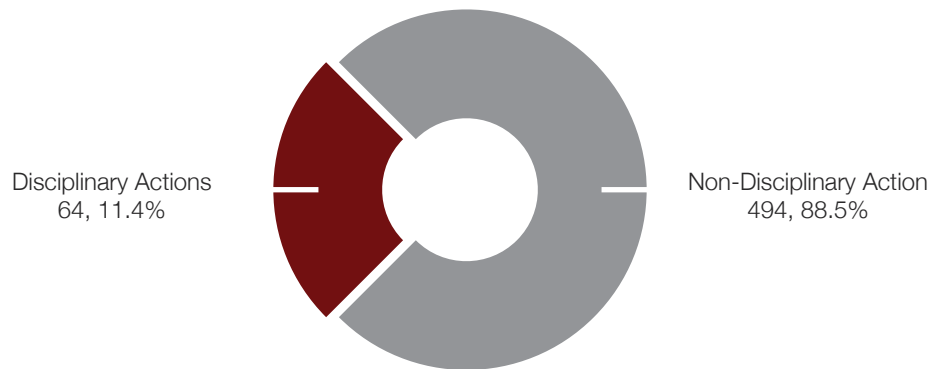
Complaint Summary



COMPLAINT DISPOSITIONS

The Board issued final dispositions on approximately 574 complaints/cases in FY21, representing a 7% decrease from FY 21. The decrease is likely attributable to the overall decline in FY 21 complaints and a significantly lower number of tax compliance complaints being referred by the Missouri Department of Revenue. Approximately 2.8% of disposed complaints involved Department of Revenue tax compliance cases (16 cases). The remaining 558 non-tax cases were disposed of as follows:

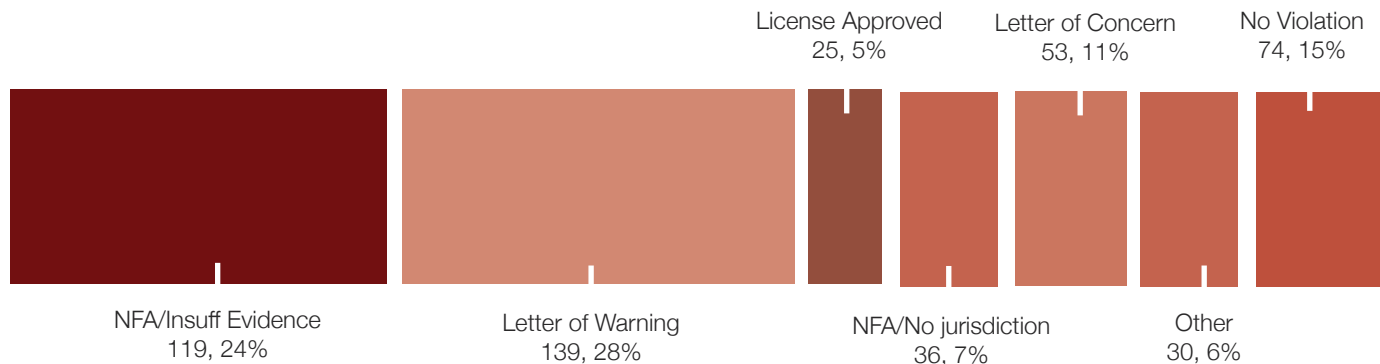
(Non-Tax Related Complaint Dispositions)



**The 558 complaint dispositions includes complaints received in prior fiscal years but finally determined in FY 21. As a result, complaint dispositions in FY21 will not equal the number of new complaints received.

SUMMARY OF NON-DISCIPLINARY COMPLAINT RESOLUTIONS:

The following action was taken in the 494 non-tax related complaints closed without disciplinary action in FY 21 (see Disciplinary Action section for complaints closed with disciplinary action):



* Other: Cease & Desist (2), Closed (13), Closed but Flagged for Future Review (11), Voluntary Surrender (4).

Disciplinary Actions

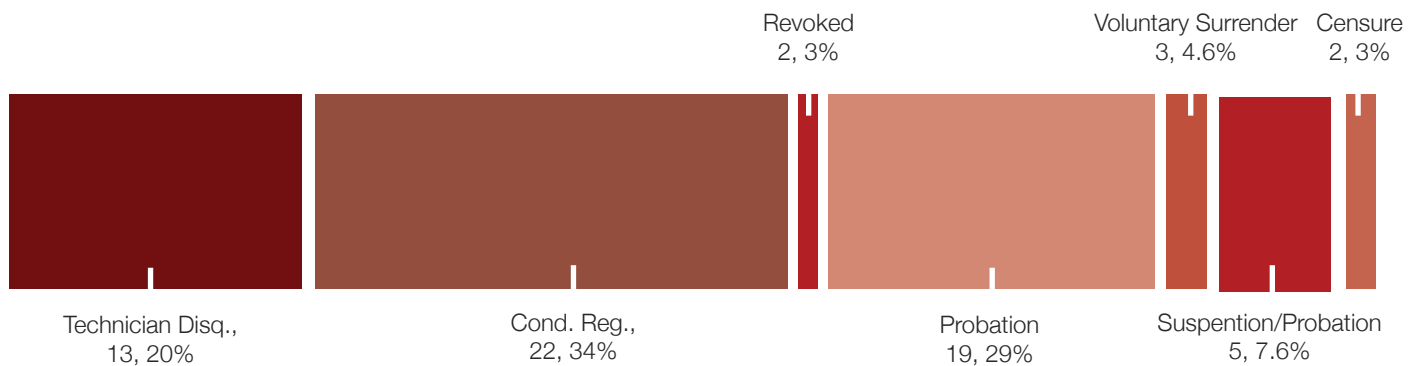


Summary of Disciplinary Action

The Board issued 81 disciplinary actions in FY 21, with 16 tax-related suspensions and 65 practice-related disciplinary actions.

Practice related discipline remained stable with a slight 1.5% increase. Tax-related disciplinary cases increased from zero (0) cases in FY 20 to sixteen (16) tax-related suspensions/actions in FY 21, as the Dept. of Revenue resumed referrals of tax-related cases. Despite the increase, total tax-related disciplinary cases were 60% lower than FY19 and 94.6% lower than FY18.

The following disciplinary action was taken in the sixty-five (65) practice-related disciplinary actions issued in FY 21:



DISCIPLINARY ACTIONS BY CATEGORY

Drug Distributors Probated	3
Drug Outsourcer Probated	1
Intern Pharmacist Licenses Voluntarily Surrendered (Treated as Discipline)	1
Intern Pharmacist Licenses Revoked	1
Pharmacist Licenses Censured	2
Pharmacist Licenses Probated	8
Pharmacist Licenses Revoked	1
Pharmacist Licenses Suspended Followed by Probation	5
Pharmacist Licenses Voluntarily Surrendered (Treated as Discipline)	2
Pharmacy Permits Probated	6
Technicians Disqualified	13
Technicians Placed on Conditional Employment	22
TOTAL	65

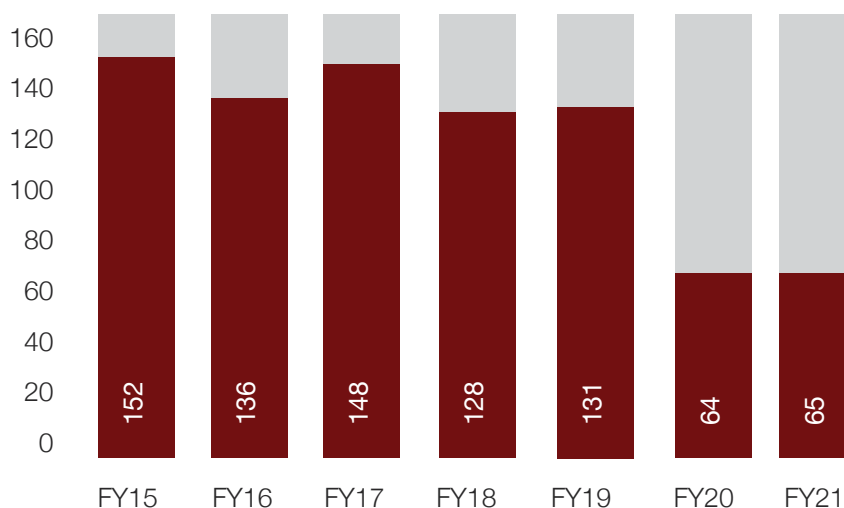
Disciplinary Actions



PRACTICE RELATED DISCIPLINARY ACTIONS *

Thirty-five (35) pharmacy technicians, 18 pharmacists, 2 intern pharmacists 6 pharmacies, 1 drug outsourcer and 3 drug distributors, were disciplined for practice- related issues during FY 21. Total disciplinary actions remained relatively consistent with a slight increase of 1.5%

(Total Practice-Related Disciplinary Actions by FY)

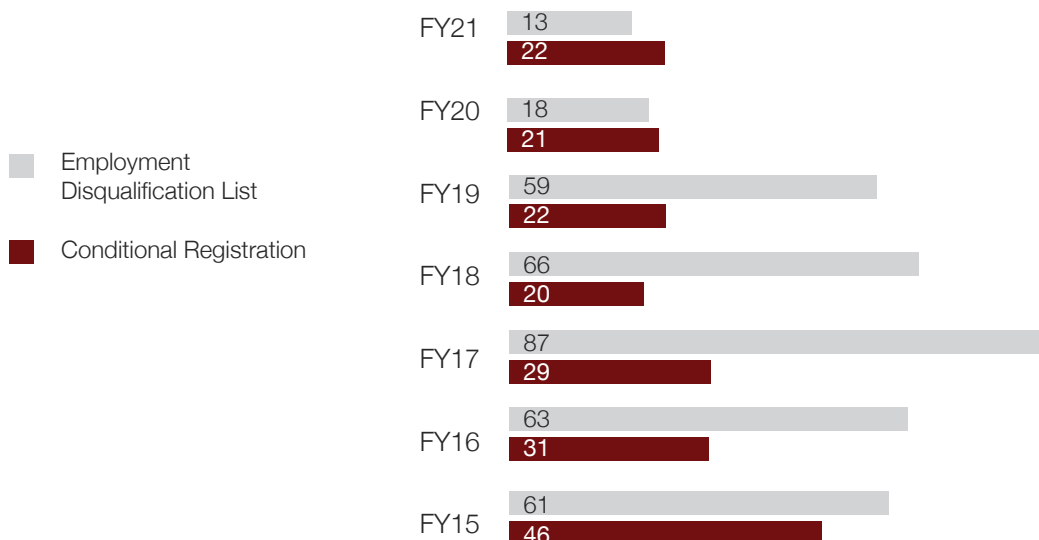


* Does not include tax suspensions pursuant to § 324.010, RSMo.

PHARMACY TECHNICIAN DISCIPLINE

Thirty-five (35) pharmacy technicians were disciplined for practice-related reasons, comprising 53.8% of all practice-related disciplinary actions issued by the Board.

(Practice Related Pharmacy Technician Discipline by FY)



Disciplinary Actions



GROUND FORS FOR TECHNICIAN EMPLOYMENT DISQUALIFICATION

(Cause for EDL / # Disciplined)

- Diversion/Attempted Diversion (8)
- Misconduct/Unauthorized Dispensing (2)
- Theft (Non-Drug Related) (1)
- Violation of Discipline (2)

GROUND FORS FOR TECHNICIAN CONDITIONAL REGISTRATION

(Cause for CR/ # Disciplined)

- Confidentiality/HIPAA Violation (1)
- Criminal History (3)
- Diversion (1)
- Illegal Drug Usage/Positive Drug Test (1)
- Misconduct/Unauthorized Dispensing (3)
- Theft (Non-Drug Related) (13)

PHARMACIST DISCIPLINE BY FY:

Pharmacist practice-related discipline increased by 12%, with a total of eighteen (18) pharmacists disciplined in FY 21. Significantly, the total number of disciplined pharmacists represents less than 0.15% of Missouri-licensed pharmacists at the close of FY 21.

	FY15	FY16	FY17	FY18	FY19	FY20	FY21
Censure	5	6	6	3	11	5	2
Probation	5	14	13	15	10	6	8
Suspension	2	0	0	0	0	0	0
Suspension/Probation	4	4	0	1	0	2	5
Revocation	1	3	1	1	1	2	1
Voluntary Surrender (treated as discipline)	--	--	4	1	4	1	2
TOTAL	17	27	24	21	26	16	18

Disciplinary Actions



PHARMACY DISCIPLINE BY FY

Pharmacy discipline decreased by 25% as reflected below:

	FY15	FY16	FY17	FY18	FY19	FY20	FY21
Censure	9	4	0	4	0	1	0
Probation	12	8	7	9	15	5	6
Revocation	0	2	0	0	0	0	0
Voluntary Surrender	0	0	0	2	1	2	0
TOTAL	21	14	7	15	16	8	6

DRUG DISTRIBUTOR DISCIPLINE BY FY

Total drug distributor disciplinary actions remained historically low, as reflected below:

	FY15	FY16	FY17	FY18	FY19	FY20	FY21
Censure	0	0	0	0	0	0	0
Probation	3	1	0	4	6	1	3
Voluntary Surrender	0	0	0	0	0	0	0
TOTAL	3	1	0	4	6	1	3

Inspections/Investigations

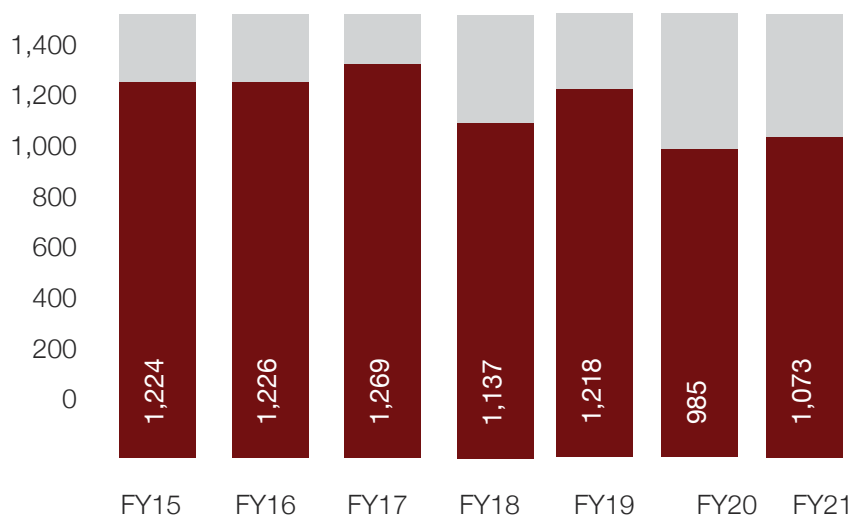


Inspection/Investigation Summary

The Board conducts new and routine inspections of all Missouri located pharmacies, drug distributors, drug outsourcers and third-party logistics providers. Board inspectors also conduct investigations as assigned.

- The Board resumed a modified inspection schedule in FY 21 as part of its continued COVID-19 precautions, with limited inspections of COVID-19 high risk facilities (e.g., long-term care, infusion/chemotherapy facilities)
- Under the modified inspection schedule, 1,073 regulatory inspections were conducted, representing a 10% increase from FY 20. The Board anticipates returning to a full inspection schedule in 2022.
- 918 pharmacy, 144 drug distributor, 1 drug outsourcer and 10 third-party logistics provider inspections were conducted. Fourteen (14) entities were exempt from inspection as state facilities or as authorized by 20 CSR 2220-5.040 for facilities inspected by the U.S. Food and Drug Administration (13 drug distributors, 1 outsourcer).
- Despite COVID-19 restrictions, total investigations remained consistent with a minor 2.3% decrease (206 investigations).

FY 20 - Pharmacy/Drug Distributor Inspection Summary



INSPECTION FINDINGS

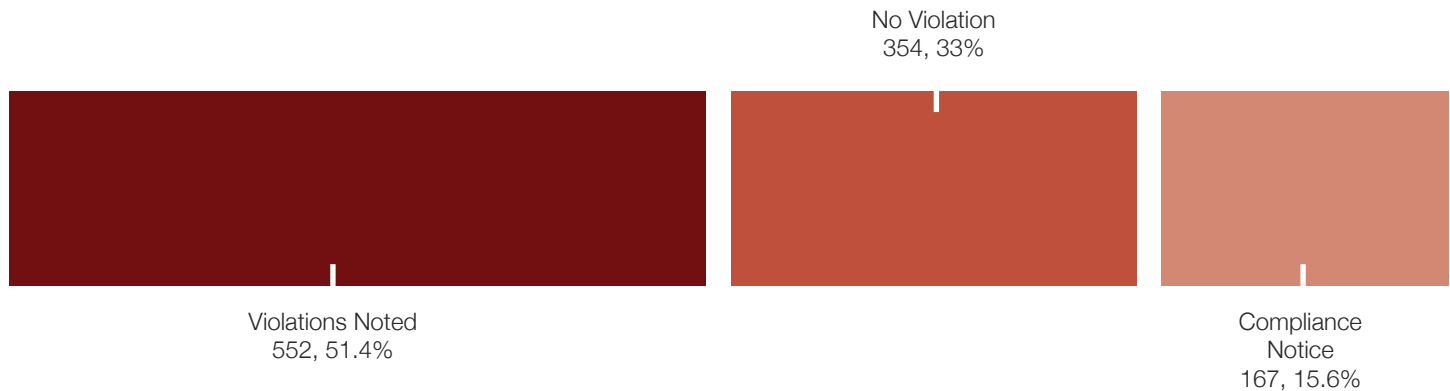
At the conclusion of an inspection, an inspector may initiate one of the following resolutions:

- **Observation Report:** Issued if no compliance issues are identified at the time of inspection or if compliance violations are noted that can generally be corrected and do not require further review/documentation.
- **Compliance Notice:** Issued if compliance concerns are discovered that require official documentation of corrective measures or in instances of multiple or repeat compliance violations.
- **Quality Assurance Report:** Issued if there is a specific question regarding the dispensing/handling of a particular prescription and/or drug.
- **Investigation:** An investigation may be initiated during an inspection if additional factual information may be necessary to assess compliance.



FY20 INSPECTION RESULTS*

Approximately 67% of Board inspections resulted in violations noted or a compliance notice being issued as reflected below:

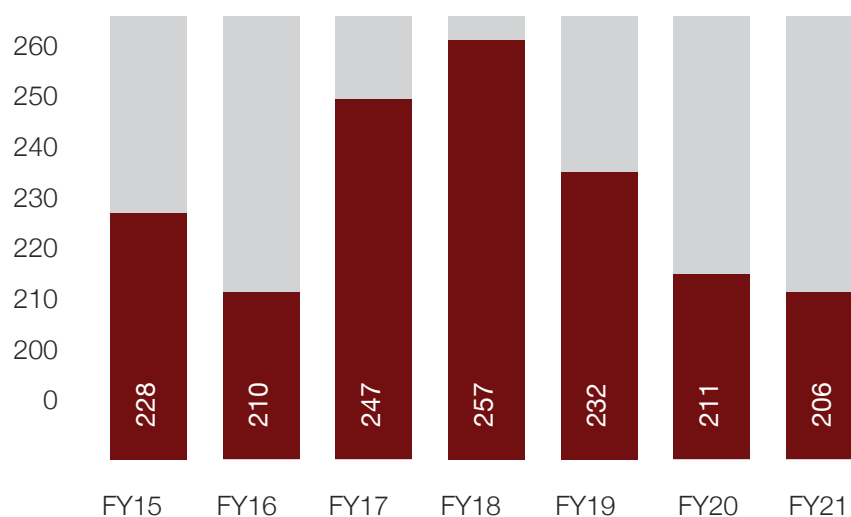


Inspection results in each category remained statistically consistent (e.g., no violation, violations noted, compliance notices).

** Includes inspection results for follow-up inspections and investigations.*

FY 20 INVESTIGATION SUMMARY

Despite COVID-19 restrictions, total investigations remained consistent with 206 investigations completed during the fiscal year (-2.3%).



Compounded Drug Testing



Testing Summary

Pursuant to § 338.150, RSMo, the Board operates a program to test drug preparations compounded by pharmacies. All preparations are tested for potency and, if applicable, sterility and endotoxins. The tables listed below are for the fiscal year ending June 30, 2021:

Dosage Form	Tests Performed
Capsule	19
IV Solution	5
Inhalation Solution	2
Injectable	4
Ophthalmic Solution	1
Oral Suspension	10
Rapid Dissolve Tablet	1
Topical Cream/Ointment/Gel	16
Topical Solution	1
Troche	2

Test Results	Tests Performed	Percentage
Satisfactory	45	73.8%
Unsatisfactory	16	26.2%
Total	61	100%

All unsatisfactory results were related to potency failures. An acceptable potency range is considered +/- 10% of the expected potency, unless a U.S.P. monograph states a different range for a specific preparation. Failing potency results ranged from zero to 124.8%. Pharmacies are notified of unsatisfactory results and asked to complete a quality assurance review of their compounding practices and provide a corrective action plan.

Drugs With Unsatisfactory Results
Naltrexone
Ketotifen
Estradiol
Sulfasalazine
5-Fluorouracil/Salicylic Acid
Bi-Estrogen/Progesterone
Diphenhydramine HCl/Haloperidol/Lorazepam
Benzoyl peroxide/Menthol/Clquinol
Benzoyl peroxide//Clquinol
Nystatin/Triamcinolone/ Benzoyl peroxide/Menthol/Clquinol
Mupirocin/Betamethasone Val/Clotrimazole/Ibuprofen
Lidocaine/Tetracaine



Rule Changes

The Board continued to review Missouri's pharmacy rules to ensure appropriate and consistent regulation and to adopt a standards of practice approach that is focused on:

- Establishing standards of practice to ensure patient safety
- Eliminating unnecessary regulatory requirements, and
- Maximizing pharmacist skill, training and education to enhance patient access to care.

Additionally, the Board reviewed its rules to ensure prompt access to care during the COVID-19 pandemic. The following rules were promulgated/amended by the Board in FY21:

Promulgated Rules

20 CSR 2220-2.120 (Amended)	Transfer of Prescription or Medication Order Information	Updated prescription transfer requirements/ timeframes and recognized designated licensure exemptions for Class C Long-Term Care Pharmacies
20 CSR 2220-2.145 (Amended)	Minimum Standards for Multi-Med Dispensing	Extended authorized beyond-use-dates for patient med paks and allows controlled substance med pak dispensing in compliance with applicable state/federal law
20 CSR 2220-2.195 (New)	Prospective Drug Utilization Review	Requires a pharmacist drug utilization review for all prescriptions/medication orders to assess therapeutic appropriateness
20 CSR 2220-2.680 (New)	Class R-Remote Dispensing Site Pharmacy	Defines licensing/compliance requirements for Class-R Remote Dispensing Site pharmacies. *Implements 2020 Legislation
20 CSR 2220-2.710 (Emergency & New Rule)	Pharmacy Technician and Intern Pharmacist Supervision	Defines required pharmacy technician/ intern pharmacist supervision. Allows technology-assisted supervision as identified in rule. *Emergency rule filed in FY 20 due to COVID-19
200 CSR 2220-2.725 (New)	Remote Data Entry	Authorized & established requirements for remote data entry by pharmacy staff outside of a licensed pharmacy. *Emergency rule filed in FY 20 due to COVID-19



20 CSR 2220-3.040 (Amended)	Return and Reuse of Drugs and Devices	Updates rule requirements; Adds return-to-stock allowances for medication filled by an automated filing system unit but not dispensed to the patient.
20 CSR 2220-5.020 (Emergency & Amended Rule)	Drug Distributor Licensing Requirements	Exempts facilities from drug distributor licensure if the facility is distributing medication into Missouri to treat/immunize patients during a state or federally declared emergency/disaster or distributing medication/vaccines subject to FDA emergency use authorization for a public health emergency. *Emergency rule filed due to COVID-19
20 CSR 2220-6.040 (Emergency & Amended Rule)	Administration by Medical Prescription Order	Amended to allow pharmacy technicians to administer vaccines by prescription order under the direct supervision of a Missouri-licensed pharmacist. *Emergency rule filed due to COVID-19
20 CSR 2220-6.050 (Emergency Rule)	Administration of Vaccines Per Protocol	Amended to allow pharmacy technicians to administer vaccines by protocol under the direct supervision of a Missouri-licensed pharmacist. *Emergency rule filed due to COVID-19
20 CSR 2220-6.055 (Amended)	Non-Dispensing Activities	Authorized pharmacy technicians to assist a pharmacist with non-dispensing activities outside of a pharmacy. *Emergency rule filed in FY 20 due to COVID-19
20 CSR 2220-6.200	Pharmacist Authority to Prescribe Pursuant to Section 338.665	Established standards/requirements for pharmacists prescribing nicotine replacement therapy products, as authorized by § 338.665. *Implements 2019 Legislation



Strategic Initiatives

As part of its regulatory mission, the Board continued its efforts to protect Missouri citizens and enhance Board operations.

LEGISLATIVE PROPOSALS

The following legislative proposals were approved by the Board for the 2021 legislative session:**

- **Emergency Response Authority:** Allows pharmacists to order and administer medication as approved or authorized by the U.S. Food and Drug Administration (FDA) to address a public health need during a state/federally declared public health emergency, or as authorized by the Missouri Department of Health and Senior Services to address a public health need.
- **Pharmacist Immunization Authority:** Allows pharmacists to administer all FDA approved vaccines to patients age seven (7) and above under protocol with a Missouri-licensed physician, or pursuant to a statewide standing order issued by the Missouri Department of Health and Senior Services, or a protocol approved by the medical staff committee of a Missouri-licensed hospital or long-term care facility.
- **Pharmacist Medication Therapy Services Authority:** Allows pharmacists to provide medication therapy (MT) services under protocol with a Missouri-licensed physician without requiring an additional patient-specific prescription. Also allows pharmacists to provide MT services pursuant to a statewide standing order issued by the Missouri Department of Health and Senior Services, or a protocol approved by the medical staff committee of a Missouri-licensed hospital or long-term care facility.
- **Technician Regulation:** Codifies the Board's ability to establish requirements for Missouri-registered pharmacy technicians performing designated activities.
- **Continuing Education:** Requires pharmacists to complete 30-hours of continuing education each biennial renewal period, in lieu of 15-hours each renewal year. (The proposal would codify current Board enforcement procedures)

** Legislative proposals are subject to Governor approval.

Compliance:

The Board continued its campaign to encourage and promote compliance and patient safety. The Board sponsored/ hosted the following free continuing education webinars in FY 21:

- 2021 New Graduate/MPJE Testing Updates
- 2021 Regulatory Update
- 2021 COVID-19 & Regulation Update
- 2020 Chief Inspector Compliance Update (Q&A Session)
- 2020 Legislative Update
- 2020 MO HealthNet Update

** Section 324.035, RSMo, was enacted in FY 20 which prohibits professional/occupational boards within the Division of Professional Registration from using Board funds to provide designated continuing education classes.

In 2017, the Missouri General Assembly enacted the Rx Cares for Missouri Program within the Board of Pharmacy to promote medication safety and to prevent prescription drug abuse, misuse and diversion in Missouri. Simultaneously, § 338.142, RSMo, was enacted which granted the Board authority to establish a drug take-back program for controlled substances, in consultation with the Missouri Department of Health and Human Services. The Board subsequently established the statewide Rx Cares for Missouri Medication Destruction and Disposal Program (the Program) for the collection of unused/unwanted medication.

Pursuant to state contract, the Program is managed/operated by Sharps Compliance® under the supervision of the Board. The Program plays a critical role in combatting the opioid epidemic by providing safe options for patient disposal of unused or unwanted medication. Eligible program participants include:

- A licensed Missouri pharmacy or drug distributor
- A licensed healthcare provider authorized to prescribe controlled substances
- A hospital, office, clinic, or other medical institution that provides health care services
- A federal, state, local, or municipal public health, law enforcement, or other governmental agency, or
- A higher education institution located in Missouri that is accredited by a national or regional accrediting body recognized by the United States Secretary of Education. [20 CSR 2220-2.990]

Program participants must be approved by the Board. Once approved, participants are provided a medication collection receptacle that complies with state and federal controlled substance laws. Collected medication can be mailed/submitted to an approved Sharps Compliance® vendor up to twelve (12) times per year at no cost to the participant.

- Program expenditures totaled \$ 126,900 in FY 21
- Participants in the statewide medication destruction Program increased by 53% from sixty-two (62) participants in FY20 to ninety-five (95) participants in FY 21 (see FY 21 participants below)
- Approximately 5,443 pounds of medication were destroyed during the fiscal year as part of the Program, representing a 550% increase from the Program's first full implementation year in FY 20.
- by the United States Secretary of Education. [20 CSR 2220-2.990]

2021 Rx Cares Medication Destruction Program Participants

Advance Pharmacy	CareSTL Health #3
AuBurn Pharmacy #210	Children's Mercy Employee Wellness Ctr
AuBurn Pharmacy #215	County Market Pharmacy 392
AuBurn Pharmacy #230	D&H Drug Store - Broadway
AuBurn Pharmacy #245	D&H Perscription Drug
AuBurn Pharmacy #250	Eldon Drug Company
AuBurn Pharmacy #255	Evans Drugs
AuBurn Pharmacy #265	Family Medicine Pharmacy
AuBurn Pharmacy #270	Flow's Pharmacy
AuBurn Pharmacy #280	GOOD GRACES PHARMACY
Austin Plaza Pharmacy, Inc.	Gower Family Pharmacy
CareSTL Health #1	Green Hills Pharmacy

Greenfield Pharmacy
Hendrick Medical Center
Hines Street Pharmacy
Hometown Pharmacy - Marshall
Key Drugs - Dexter
Key Drugs - Poplar
Lake Regional Pharmacy - CMC
Lake Regional Pharmacy - Eldon
Lake Regional Pharmacy - Lake Ozark
Lake Regional Pharmacy - Laurie
Lake Regional Pharmacy- Laurie
Lake Regional Pharmacy-Osage Beach
Lakeland Pharmacy #7
Lemonaid Community Pharmacy
Marceline Family Pharmacy
Medical Center Pharmacy
Medicenter Pharmacy
Medley Pharmacy - Gerald
Medley Pharmacy - Owensville
Mercy Pharmacy - Joplin
Mercy Pharmacy - Kennerly
Mercy Pharmacy - Nixa
Mercy Pharmacy - SGC
Mercy Pharmacy - Springfield
Mercy Pharmacy Evans Road
Mercy Pharmacy St. Robert
Mizzou Pharmacy - Keene Street
Mizzou Pharmacy - University Hospital
North End Family Pharmacy
Northwest Pharmacy Services
Ozarks MCEP

Parkland Health Mart Pharmacy
Parkland HM Phcy. - Piedmont
Phelps Health Employee Pharmacy
Praters Pharmacy - Sarcoxie
Prater's Pharmacy - Seneca
Rogers Pharmacy
Rogersville Pharmacy
Saint Luke's East Hospital
Saint Lukes of KC - Children's Center
Saint Lukes of KC - Children's Center
Sam's Health Mart Pharmacy # 2
Sam's Health Mart Pharmacy # 3
Sam's Health Mart Pharmacy #1
Savannah Family Pharmacy
Scotland County Pharmacy
Sherri's Pharmacy Service, INC
Sinks Pharmacy - 10th St.
Sinks Pharmacy - Bourbon
Sinks Pharmacy - South
Sinks Pharmacy - St. Clair
Sinks Pharmacy - Sullivan
Sinks Pharmacy - Vienna
Sinks Pharmacy - Waynesville
SINKS PHARMACY-BELLE
SSM Health - DePaul Hospital
SSM Health - SJH - Lake St. Louis
SSM St. Clare Health Center
St Luke's North Hospital
St. Joseph Outpatient Pharmacy
St. Louis Hills Pharmacy
St. Louis Pharmacy

Rx Cares for Missouri Program



St. Louis Pharmacy at IC

Steelville Drug

Stephens Pharmacy at CMH

The Drug Store

The Medicine Shoppe - Poplar Bluff

Twin City Pharmacy

West Pine Pharmacy

Wright Memorial Hospital

York and Co. Pharmacy

